REMARKS

I. Status of Claims

Claims 1-59 are pending in this case and claims 31-59 were withdrawn from consideration pursuant to a restriction requirement. Claim 1 was amended to recite that at least one active agent chosen from anti-seborrhoeic active agents and anti-acne active agents is applied to an area in need of treatment. Support for this amendment can be found at least on pages 2 and 3 of the application.

II. Claim Rejection under 35 U.S.C. § 112, first paragraph

The Office continues to maintain the rejection of claims 1-30 under 35 U.S.C. § 112, first paragraph, as lacking support to enable the method of treating all disorders associated with seborrhea and all disorders associated with the microorganisms of the genus *Propiobacterium*. Office Action at pages 2-4. In response to Applicants' argument that the Office failed to consider all the *Wands* factors, the Office asserts that enablement requires a balancing test of facts available to one of ordinary skill in the art and in this case, the facts favor the rejection. *Id.* at page 4. In addition, the Office contends that in the specification, there are no working examples or guidance as to how to make/use the claimed invention with respect to all the claimed skin disorders. *Id.* Applicants continue to respectfully disagree, particularly with the extent to which the specification must provide a working example with respect to all the claimed skin disorders.

Under M.P.E.P. § 2164.01(b), as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation

to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied. M.P.E.P. § 2164.01(b) (8th ed. Rev. 2, 2004) (citing *In re Fischer*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (C.C.P.A. 1970)). In this case, Applicants' specification provides for numerous examples that bear a reasonable correlation to the scope of the claims.

As set forth in the specification at page 2, the present invention provides for the use of at least one polyamino acid derivative of formula (I) for the *cosmetic treatment* of seborrhea of the *skin and scalp*, and *skin disorders* associated with seborrhoea, and of *skin disorders* associated with the microorganisms of the genus *Propionibacterium*, such as *Propionibacterium acnes* and *Propionibacterium granulosum*. Specification at least on page 2, lines 5-9. The specification further provides working examples, among other things, directed to *Propionibacterium acnes* and *Propionibacterium granulosum*. *See, e.g.*, Specification at pages 13-15. Because a genus typically is identifiable based on common attributes, testing a species within that genus can demonstrate a reasonable correlation to the scope of the claims. *See* The American Heritage College Dictionary 569 (1993). As such, working examples directed to *Propionibacterium acnes* and *Propionibacterium granulosum* should bear a reasonable correlation to the scope of the claims, i.e., *Propionibacterium*. Accordingly, Applicants respectfully request the withdrawal of this rejection.

III. Claim Rejection under 35 U.S.C. § 102(e)

The Office also rejects claims 1-10, 12-15, 25-27, and 30 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,395,284 to Thunemann ("Thunemann") as evidenced by Aldrich (1996-1997). Office Action at page 5. The Office withdrew the rationale used in the previous Section 102(e) rejection because it failed to appropriately use the second reference. *See id.* at page 2, ll. 8-10. The Office, however, issued a new rejection correcting the previous problem and thus, essentially maintained the Section 102(e) rejection. As such, Applicants respectfully disagree and traverse the rejection for the following reasons.

In response to our argument that Thunemann fails to teach all the claimed limitations, the Office asserts that "the presence of vitamin A in the Thunemann composition does not in any way affect the teaching that the use of the polyamino acid compound to treat acne is well known in the art." *Id.* at page 6. Applicants respectfully disagree.

A compound or composition of matter is anticipated if the disclosure in a single reference places that compound or composition in possession of the public. *See In re Brown*, 329 F.2d 1006, 1011, 141 U.S.P.Q 245, 249 (C.C.P.A. 1964). The reference must "clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures . . . ." *In re Arkley*, 455 F.2d 586, 587, 172 U.S.P.Q. 524, 526 (C.C.P.A. 1972). Thus, the reference must provide a certain degree of precision with respect to the specific compound claimed.

In this case, Thunemann fails to provide the requisite degree of precision with respect to the claimed invention. Specifically, Thunemann states that "vitamin A acid is used for the external treatment of severe cases of acne, and its use for courses of skin rejuvenation has also been suggested." Thunemann at Col. 1, ll. 31-33. As such, Thunemann identifies that one of the major problems faced with administering vitamin A is the need for immobilization. *Id.* at Col. 1, ll. 46-48. Thus, Thunemann discloses mesomorphic complexes of vitamin A acid with cationic polyelectrolytes to assist in immobilization. *Id.* at Col. 2, ll. 10-13. In fact, Thunemann discloses the use of vitamin A with three different polyelectrolytes that are preferable. *Id.* at Col. 2, ll. 41-43. The Office asserts that because these polyelectrolytes are used with the active agent, vitamin A acid, to treat acne then one could use any one of the polyelectrolytes alone to treat acne. This picking and choosing of a polyelectrolyte alone is not taught nor suggested by Thunemann.

Thunemann specifically identifies vitamin A as the "pharmacological active substance," not the cationic polyelectrolytes. *See, e.g.*, Thunemann at Col. 1, ll. 26-40. Thunemann provides that "the complexation of vitamin A acid with cationic polyelectrolytes is based on the finding that the formation of ordered structures in solution or in the solid state often takes place by means of self-organization by attachment of a surface-active agent to a polyelectrolyte." *Id.* at Col. 2, ll. 13-17. It is this complex that allows for the immobilization of vitamin A acid. This disclosure does not suggest or teach the use of these three different polyelectrolytes individually.

Thunemann states that three preferred polyelectrolytes are: (1) PDADMAC (poly(dimethyldiallylammonium chloride); (2) PM4VP (poly(N-methyl-4-vinyl-pyridine

chloride); and (3) poly-L-amino acids. *Id.* at Col. 2, line 44-Col. 3, line 5. These cationic polyelectrolytes are used for the immobilization of vitamin A, and the release behavior of vitamin A may be adjusted based on the choice of cationic polyelectrolyte. *Id.* at Col. 2, ll. 10-13; Col. 3, ll. 5-8. Thunemann, however, does not disclose nor direct one to a particular cationic polyelectrolyte nor to the use of the polyelectrolyte as an active agent to treat acne, as interpreted by the Office.

As such, picking and choosing the disclosure of poly-L-amino acids out of mesomorphic complex with vitamin A goes against the teaching of Thunemann. Moreover, this selection is contrary to the requirements meeting a Section 102 rejection. Thus, Applicants respectfully request the withdrawal of this rejection.

IV. Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: December 2, 2004

By: _____
Adriana L. Burgy
Reg. No. 48,564